United States Court of Appeals

for the Second Circuit

APPELLEE'S BRIEF

official

B

74-1738

To be argued by
NAOMI REICE BUCHWALD

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 74-1738

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs-Appellants,

—v.—

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

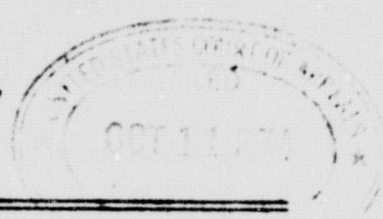
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF OF DEFENDANTS-APPELLEES

PAUL J. CURRAN,
United States Attorney for the Southern District of New York,
Attorney for Defendants-Appellees.

NAOMI REICE BUCHWALD,
GERALD A. ROSENBERG,
Assistant United States Attorneys,
Of Counsel.



2

TABLE OF CONTENTS

TABLE OF CASES

STATUTES CITED

Other Authorities

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 74-1738

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs-Appellants,

—v.—

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

BRIEF OF DEFENDANTS-APPELLEES

The Issues on Appeal

1. Did the Food and Drug Administration have the authority to issue the challenged regulations?

2. Is the "arbitrary and capricious" review standard of the Administrative Procedure Act applicable to the challenged regulations?

3. Are the challenged regulations supported by the administrative record before the Food and Drug Administration?

A. Are Vitamins A and D at the regulated levels "drugs" within the meaning of Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1)?

B. Are Vitamins A and D at the regulated levels properly classified as prescription drugs within the meaning of Section 503(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 353(b)(1)?

4. Did the district court err in granting defendants' motion to vacate the notice of deposition directed to defendant Alexander M. Schmidt, Commissioner of Food and Drugs, or his designee?

Statement of the Case

This is an appeal from an order of the Honorable Marvin E. Frankel, United States District Judge, dated and filed April 5, 1974, granting defendants' motion for summary judgment and dismissing plaintiffs' complaint.* In the same opinion, Judge Frankel granted defendants' motion to vacate a deposition notice served by plaintiffs and directed to defendant Alexander M. Schmidt (Joint Appendix, 370a-390a).**

Essentially, plaintiffs' complaint alleges that the Food and Drug Administration's ("FDA") regulations which require dispensation on a prescription basis of pills containing in excess of 10,000 international units ("IU") of

---

* An opinion rendered by Judge James B. Parsons upheld these regulations against a challenge similar to the one proffered here. *National Health Federation* v. *Weinberger*, No. 73 C2466 N.D. Ill., March 22, 1974). The plaintiff in that case was granted leave to appear *amicus* in this case by order of this Court, dated August 22, 1974. For a description of the panoply of activities of the National Health Federation, which represented to the Court that it is "America's largest, noncommercial health consumer group" see House Comm. on Interstate and Foreign Commerce, Comm. Print No. 11, 93d Cong., 1st Sess. 82-88 (1973) and Hearings Before the Subcomm. on Public Health and Environment of the House Comm. on Interstate and Foreign Commerce on H.R. 643 et al. (Oct. 29, 30 and 31, 1973).

** All subsequent page references, unless otherwise noted, are to pages in the Joint Appendix. All references with the prefix "E" are to pages in the Exhibit Volumes.

Vitamin A or in excess of 400 IU of Vitamin D are unauthorized by statute and that their enforcement should be enjoined. The challenged regulations, 21 C.F.R. § 3.94 and § 3.95, require that high potency vitamin products labeled after October 1, 1973 reflect their prescription status and contain warnings as to their toxicity (34a).

Plaintiffs' motion for a preliminary injunction, filed prior to the effective date of the regulations, was denied by Judge Frankel on September 25, 1973 (330a-346a), 366 F. Supp. 1341. Following a careful examination of the record, this Court affirmed the District Court's denial of a preliminary injunction "for the reasons stated in Judge Frankel's comprehensive opinion" (347a-349a). 491 F.2d 845. Thus, the regulations have been in effect since October 1, 1973.

Contrary to the contentions of plaintiffs, it is the position of the defendants, supported by the Court below, that the type of regulations issued were authorized and contemplated by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("the Act") and that the specific regulations were neither in excess of the Commissioner's authority nor arbitrary and capricious, because Vitamins A and D are drugs within the meaning of the Act and at the high levels regulated properly classified as prescription drugs.

Statement of Facts: The Challenged Regulations

When the Commissioner of the Food and Drug Administration proposed the challenged regulations in the Federal Register * of December 14, 1972 (35a-37a), his action was based upon growing evidence contained in FDA

---

* The contents of the Federal Register are required to be judicially noticed. 44 U.S.C. § 1507. *Wei* v. *Robinson*, 246 F.2d 739, 743 (7th Cir.), *cert. denied*, 355 U.S. 879 (1957).

files and "documented extensively in the medical literature" (35a), which led him to conclude that large quantities of Vitamins A and D are acutely and chronically toxic. That medical literature, which was on file with the Hearing Clerk, Department of Health, Education and Welfare, (35a) is now before this Court in Exhibit Volumes I and II, pp. E1-E691 (367a-369a).*

Large dosages of Vitamin A and/or Vitamin D ingested over long periods of time can cause adverse effects, some of which are serious. Specifically for Vitamin A, consumption of "dosages of 50,000 IU in adults and 20,000 IU in infants on a daily basis over long periods are known to produce toxicity" (36a) For Vitamin D, the harm caused by ingestion of large dosages is also documented:

> "Daily ingestion by infants of doses between 1,000 and 2,000 IU has produced hypervitaminosis D, usually manifested as the infantile hypercalcemia syndrome. There is good evidence suggesting that the supravalvular aortic stenosis syndrome with hypercalcemia in infants and children may result from excess intakes of vitamin D by the infant and/or by the mother during pregnancy. This latter syndrome may have a tragic outcome with severe aortic stenosis, mental and physical retardation, elfin facies, renal failure and death" (36a).

Among the adverse effects from excessive intake of Vitamin A which the Commissioner listed were: growth retardation in children, migratory arthralgia, hepotosplenomegaly (enlargement of spleen and liver), alopecia (loss of hair) and drying and cracking of skin. In addition, in-

---

* Indeed, those articles formed the basis for the letter of comment submitted on behalf of plaintiff, National Nutritional Foods Association (38a-54a).

creased intercranial pressure, which may mimic a brain tumor, was another adverse effect noted by the Commissioner * (35a-36a).

Noting that "generally, the margin of safety between nutritional requirements and toxic levels is small for Vitamin D", the Commissioner detailed the consequences of hypervitaminosis D:

> "anorexia, nausea, weakness, weight loss, polyuria, constipation, vague aches, stiffness, generalized vascular, soft tissue and premature epiphyseal calcification, nephrocalcinosis, hypertension, anemia, hypercalcemia, acidosis, irreversible renal failure and death" (36a):

The medical articles that comprise Exhibit Volumes I and II speak eloquently of the need for regulation in the dispensation of vitamins to the public. Those articles document the consequences of overconsumption of Vitamins A and D. The Joint Committee Statement of the Committees on Drugs and Nutrition of the American Academy of Pediatrics appearing on pages E365-E366 summarizes in laymen's language the causes and effects of hypervitaminosis A. On pages E261-262 there appears a charted summary of reported cases of chronic Vitamin A intoxication. Summaries of studies of the effects of the overconsumption of Vitamin D are contained in the articles appearing at Pages E648-652 and E664-691.

Perhaps the most striking cases of Vitamin A and D overdose involve victims who followed the presumably sensible maxim that "if one is good two are better" (E217, E366). England literally poisoned its infant population by fortifying its milk and cereal with Vitamin D, causing

---

* This particular symptom has been found especially among teenagers who have used large dosages of vitamin A in attempts to cure acne.

a veritable epidemic of idiopathic hypercalcemia during the 1950's (E477, E649, E676-77) On a less massive scale the "conscientious mother may unwittingly overdose her child" (E217); the teenager anxious about his acne will ignore the advise of his physician and the dosage warnings on the Vitamin A bottle (E256, E258, E275-276, E363). Nor are the cases limited to the young. Included in the studies are that of an elderly man acting on the advise of a friend who probably killed himself by consuming too much Vitamin D (E398-401); a 38-year old woman who gave herself a case of hypervitaminosis A after taking Vitamin A to improve her vision (E299-303) and a 41-year old judge who was hospitalized after taking large dosages of Vitamin D to treat his arthritis (E552-556).

Nonetheless, despite the acknowledged danger of large dosages of Vitamins A and D, these vitamins were available to the public over-the-counter at levels vastly in excess of the danger quantities. Vitamin A was available, and indeed was manufactured by plaintiff Solgar Co., in 50,000 IU capsules (320a, 321a-325a). Each such capsule contains ten times the Recommended Dietary Allowance ("RDA") for Vitamin A set by the Food and Nutrition Board, National Academy of Sciences—National Research Council ("NAS-NRC"). Vitamin D was available over-the-counter in dosages of 25,000 IU per pill. That level is far in excess of the dosage level which causes a toxic reaction and is more than sixty times the RDA even for women during pregnancy and lactation (36a). For most adults, according to the NAS-NRC, there is no RDA for Vitamin D—exposure to sunlight and ordinary diet are sufficient (33a). The Commissioner's proposed Statement of Policy noted:

> "The availability without prescription of these vitamins in high dosage levels contributes significantly to their misuse and the occurrence of serious adverse effects" (35a).

Not only did the Commissioner find that Vitamins A and D were readily available to the public at levels which could cause serious harm, but he found that "there is widespread promotion to the laity of excessive quantities of these vitamins for prophylaxis and treatment of a variety of diseases and disorders" (35a). The Commissioner referred to a newsletter of the American Academy of Pediatrics which noted the recommendation of high dosages of Vitamin A in the lay press, on radio and on television. The Commissioner specified:

> "For example, the layman is being advised that he would profit from taking 25,000 international units (IU) of vitamin A with 2,500 units of vitamin D, or twice these amounts, daily" (35a).

It was against this background of well-documented medical evidence of the dangers of extended ingestion of large dosages of Vitamins A and D; the ready availability to the public of massive dosages of these vitamins and the promotion of the consumption of excessive dosages in the lay press, that the Commissioner* first proposed and later adopted these regulations.

For Vitamin A the prescription level, 10,000 IU, is two times the NAS-NRC RDA for adults and for Vitamin D the prescription level was set at the NAS-NRC RDA for women during pregnancy and lactation, most adults needing no Vitamin D other than that available in their ordinary diet and from exposure to sunlight.

The Regulations do not affect the sale of pills containing 10,000 or fewer IU of Vitamin A or 400 or fewer units of Vitamin D unless the label on the bottle containing such

---

* Section 701(a) of the Act, 21 U.S.C. § 371, authorizes the Secretary of Health, Education, and Welfare "to promulgate regulations for the efficient enforcement of this Act." This authority is delegated to the Commissioner of Food and Drugs. 21 C.F.R. 2.120(a)(1).

pills recommends daily intake exceeding those levels. Nor do the regulations prevent a person from purchasing bottles containing enormous numbers of these pills without prescription nor from consuming dosages of Vitamins A and D in excess of the prescription dosages set by the FDA. For example, a consumer who disagrees with the Regulations may purchase vitamins of non-prescription levels and consume multiple units.* Nor is the manufacturer restricted in its production of such dosage units.

During the sixty-day period for comment, the Commissioner received approximately 2,500 comments and 1,000 signatures on petitions** (32a). Plaintiff National Nutritional Foods Association submitted a comment in opposition to the proposal (38a-54a). However, commenting in favor were such distinguished medical and scientific organizations as the American Medical Association and the American Academy of Pediatrics (192a-194a). Likewise endorsing the proposal was the Oklahoma Nutrition Task Force, University of Oklahoma (152a). Indeed, other medical authorities urged even *greater* restrictions than were proposed. For example, a comment from a physician at Vanderbilt University School of Medicine, Department of Biochemistry, supported the proposal, but stated that 5,000 IU for Vitamin A (or half the proposed amount) would be a more judicious level (153a). A comment from the Department of Chemical Pathology, the United Liverpool Hospital, Liverpool, England, included a research

---

* One argument stressed in the brief of the *amicus curiae* is the restriction upon freedom of choice which results from these regulations. As recently as its decision in *National Nutritional Foods Association* v. *Food and Drug Administration*, 73-2129 et al. p. 5239 (2d Cir. August 15, 1974) this Court recognized that such restrictions, which here are very limited, are an acceptable consequence of the protection of the public good.

** All these comments and petitions were filed with the District Court.

paper written by the correspondent regarding self-medication with multivitamin preparations and recommended that 100 IU of Vitamin D (or one-quarter the proposed amount), be the limit for non-prescription marketing (154a-155a).

The Commissioner described the comments received as dividing into three general categories:

> "(1) Those who agree that the action proposed by the Food and Drug Administration is necessary and that the prescription levels proposed for vitamin A and vitamin D are suitable. Those who agreed included the American Academy of Pediatrics, the American Medical Association, the American Dietetic Association, five consumer groups, a number of physicians, dietitians, nutritionists, home economists and other professionals in the scientific and health care community, and a few individual consumers.
>
> (2) Those who agree that such vitamins can be toxic, but only at levels higher than those levels proposed by the Food and Drug Administration. The majority of the drug manufacturers and trade associations, and some consumers, made responses that were in this category.
>
> (3) Those who disagree with the proposal entirely, stating that such vitamins are foods and that individuals should have the right to ingest any amount desired. The comments from most individual consumers, operators of health food establishments and a consumer group, were in this category" (32a).

On the basis of the record and "having considered the comments received, the Commissioner conclud[ed] that the proposed regulations are in the public interest and should be adopted . . ." (34a).

ARGUMENT

POINT I

Both the legislative history of the prescription statute and the general authority of the FDA to issue regulations for the efficient enforcement of the act, give the commissioner the power to issue binding regulations to enforce the prescription provision of the act.

Apart from their arguments directed to the terms of the particular regulations in question, plaintiffs contend on appeal, as they did below, that the FDA is lacking in authority to issue any regulation substantive in nature and is limited to issuing so-called interpretative regulations under Section 701(a) of the Act, 21 U.S.C. § 371(a). According to plaintiffs, the essential difference between these two types of regulations is dependent upon whether the regulation is to have binding effect once issued. It will be demonstrated *infra* that the distinction sought to be drawn by plaintiffs is, at least in the context of this litigation, a distinction without a difference.* Whether de-

---

* Another possible distinction between substantive or interpretative regulations could be the standard of review to be applied to each. Point II of this memorandum will demonstrate that the denomination of the regulations is also without consequence in that regard. Lastly, it should be noted that the promulgation of these rules by a notice and comment procedure was sufficient whether the regulation is deemed interpretative or substantive. See 5 U.S.C. § 553(b) and (c) which provide (a) that except when notice or hearing is required by statute, publication of notice in the Federal Register is not required for interpretative rules, and (b) that the opportunity to participate in the promulgation of substantive rules (not required to be issued after statutory hearing as these are not) may be "with or

[Footnote continued on following page]

nominated substantive or procedural, the requirements for promulgation have been satisfied; the standard of review is identical and both types of regulations can be binding.

A. The legislative history of the prescription statute clearly contemplates the issuance of regulations such as those presently challenged in this action.

At the outset of this discussion of the history of the prescription drug provision of the statute, Section 503(b) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 353(b), it should be noted that Section 701(a) makes general provision for the promulgation of regulations for the efficient enforcement of the Act. 21 U.S.C § 371(a). This is significant because the legislative history of the prescription provision, known as the Durham-Humphrey Amendment, makes abundantly clear Congress' intention that the general power to issue regulations provided for in Section 701(a) of the Act was to be utilized in the enforcement of Section 503(b) of the Act, the prescription provision.

In 1951 Congress considered amendments to Section 503(b), 21 U.S.C. § 353(b), because under the existing law there was considerable confusion regarding which drugs were to be sold on prescription and which drugs could be sold over the counter. As noted in House Rep. No. 700 (246a) with respect to H.R. 3298 (a bill substantially modified) an anomaly then existed in the prescription drug field:

> "Under the present law, and the regulations issued thereunder, the initial responsibility is upon

---

without opportunity for oral presentation." Having satisfied the requirements for promulgation of both substantive and interpretative rules, Judge Friendly's comment that there is "little profit in debating the point" appears apt. *Toilet Goods Association* v. *Gardner*, 360 F.2d 677, 686 (2d Cir. 1966), *aff'd.*, 387 U.S. 167 (1967).

> the manufacturer to decide whether his drug is unsuitable for self-medication and therefore must be labeled with a caution legend (that is, a warning that the drug in question may be dispensed only by or on prescription of a physician) and may be sold only on prescription, or whether his drug is suitable for self-medication and therefore must be labeled with adequate directions for use and may be sold freely over the counter. Lack of uniformity among manufacturers in interpreting the present law and regulations has led to great confusion in the labeling of drugs for prescription sale and for over-the-counter sale" (248a).

See also, S. Rep. No. 946, 82d Cong. 1st Sess. 1-2 (283a-284a).

Broadly speaking, Congress had three possible responses to the status quo; first, it could have failed to act and left the enforcement of the law to a case-by-case, possibly litigated, resolution as then was the practice (249a-250a). Second, both the House and the Senate were presented with bills urging the immediate compilation of a comprehensive list of prescription drugs (see H. R. Rep. 700, 246a-282a and S. Rep. No. 946, 284a-287a), which listing would be preceded by "extensive hearings involving expert testimony" (254a). It is the debate on the House floor rejecting the administrative listing solution upon which plaintiffs in the main rely to support their assertion that Section 503(b) of the Act, 21 U.S.C. § 353(b) permits the FDA to issue only interpretative regulations. It is further suggested by plaintiffs that these interpretative regulations would provide the basis for case-by-case applications of the FDA standards to individual drugs (App. Brief, 34-35).

The third solution and the one finally adopted combined the use of a statutory definition of a prescription drug with the enforcement and interpretation of that definition by the issuance of Section 701(a) regulations. The Senate Report, 283a-294a, in its discussion of the proposal that actually became law, and which was issued after the changes in the bill to which plaintiffs refer, indicated that utilization

tion of Section 701(a), 21 U.S.C. § 371(a), would be necessary to make the prescription section workable.

> "In order to give this general definition a more precise meaning so that it may be applied with greater uniformity by the drug trade the Administrator can exercise the authority he has under Section 701(a) of the Federal Food, Drug and Cosmetic Act to issue interpretative regulations. It is to be understood that the inclusion of the statutory definition does not, of course, in any way derogate from the Administrator's authority to *interpret and enforce* the definition through the issuance of any regulations necessary or appropriate to protect the public from indiscriminate dispensing of drugs over the counter when they may be unsafe for use without the supervision of a practitioner licensed by law to administer such drugs.
>
> As previously stated, the committee considered S. 1186 together with H.R. 3298. S. 1186 would have authorized the Federal Security Administrator to list by name or class the drugs which he considered within the statutory definition. The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing is not necessary at this time. It was felt that the statutory definition, together with the authority to make interpretative regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration working under the statutory plan. If the present confusion is not ended by this legislation it will then be time enough to consider the need for the administrative listing approach" (S. Rep. No. 946) (emphasis added) (286a-287a).

And again:

> "The broad language of the definition contained in this sub-paragraph is intended to comprehend all drugs that in fact should be administered under medical supervision in order to insure their safe use. Such difficult borderline cases as may arise under this definition can be dealt with under the *interpretative and rule-making power* provided for in section 701(a) of the act" (emphasis added) (291a).

It should be stressed that defendants' legislative history argument is predicated upon repeated statements of similar import contained in the Senate Report issued in support of the legislation which was ultimately enacted. As such that legislative history is the most recent statement of Congress and is also under the case law the most authoritative statement of Congressional intent. *Zuber* v. *Allen,* 396 U.S. 168, 186 (1969) ("A committee report represents the considered collective understanding of those Congressmen involved in drafting and studying proposed legislation. Floor debates are at best the understanding of individual Congressmen.") See also, *United States* v. *O'Brien,* 391 U.S. 367, 385 (1968).

Thus, we respectfully submit that the legislative intent is clear: the Commissioner was to have the power to issue regulations of general application both to interpret and to enforce the statute.

B. Section 701(a) of the act authorizes the issuance of these regulations.

It is unquestioned that Congress intended that the FDA could issue regulations under Section 701(a) of the Act, 21 U.S.C. § 371(a), in connection with the prescription provision of the statute. The defendants have maintained and Judge Frankel found that the regulations issued under Section 701(a) of the Act are binding. Plaintiffs' newly

adopted position is that Section 701(a) regulations are limited only to non-binding interpretative regulations.* See Point II B of Appellants' Brief.

At least since the Supreme Court's decision in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 151-152 (1967) wherein 701(a) regulations described as interpretative were found to have the status of law and thus to have had such direct and immediate impact as to entitle the plaintiffs to pre-enforcement judicial review, it has been the law that interpretative regulations can be binding. Indeed, this Circuit citing the decision in *Abbott Laboratories*, has noted: "the Commissioner has the power to issue binding interpretative regulations." *CIBA-GEIGY Corp.* v. *Richardson*, 446 F.2d 466, 468 (2d Cir. 1971).

In that same case, this Circuit not only endorsed the view, recently reaffirmed by the Supreme Court, that particularization of a statute by rule-making is an acceptable alternative to case-by-case litigation but declared it to be the "preferred procedure." *Id.; Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 620 (1973). Such powers even though not "spelled out *in haec verba*", *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) are implicit when in their absence the administrative agency chosen by Congress to administer the Act "cannot administer the Act intelligently and rationally unless it has authority . . ." *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 624 (1973) (holding that the FDA had the authority pursuant to Section 701(a) to determine whether a particular drug is a "new drug" within the meaning of Section 201(p)(1) of the Act, 21 U.S.C. § 321(p)(1), thus subjecting the drug to preclearance by the FDA for safety and effectiveness).

---

* Clearly, this was not plaintiffs' position when they sought to preliminarily enjoin the effective date of these regulations on the ground that their effectiveness would cause plaintiffs irreparable harm (15).

The applicability of this general rule-making principle to the FDA, both because of its particular expertise and the dangers to the public of a case-by-case determination, has been recently discussed by the Supreme Court. It recognized that the technical and scientific questions involved in FDA determinations on which drugs should be classified as "new drugs" made appropriate an initial determination of the issue by the agency, subject to subsequent judicial review. *Weinberger* v. *Bentex Pharmaceuticals Inc.*, 412 U.S. 645, 653-54 (1973); *CIBA Corp.* v. *Weinberger*, 412 U.S. 640, 643-44 (1973). Such medical considerations are equally applicable to determinations of which items should be classified as drugs and which items should be regulated as prescription drugs.

A second factor in determining the type of rules which the FDA can issue under Section 701(a) of the Act is the effect upon the public of a decision that regulations issued under that section would not have binding effect. Again the comments of the Supreme Court with respect to whether the FDA had the power to determine which drugs were new drugs under the Act are apt.

> "Clearly, if FDA were required to litigate, on a case-by-case basis, the "new drug" status of each drug now marketed, the regulatory scheme of the Act would be severely undermined, if not totally destroyed. . . . In a case much more clouded with doubts than this one, we held that we would not "in the absence of compelling evidence that such was Congress' intention . . . prohibit administrative action imperative for the achievement of an agency's ultimate purposes." [citations omitted] *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).

In rejecting the contention that the FDA had to conduct a separate administrative or judicial proceeding with re-

spect to all similar drugs covered by a new drug application, the Supreme Court emphasized the effect that such an approach would have upon the public:

> "To require separate judicial proceedings to be brought against each . . . would be to create delay where in the interests of public health there should be prompt action." (*Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 625 (1973).

It was precisely the problem of individual interpretation of the prescription provision of the Act and litigation on a case-by-case basis which led to its amendment in 1951 (248a-250a, 283a-284a).

In sum, the legislative history contemplates the utilization of Section 701(a) to issue binding regulations of general applicability in accordance with the case law, which recognizes the wisdom of the issuance of such regulations by the agency entrusted with the duty of efficiently enforcing the Act in the interest of the public's health.

POINT II

The record before the district court provided a sufficient basis for review which was had under the appropriate standard.

With respect to the standard to be applied by a District Court in reviewing challenges to the regulations in question, plaintiffs argue first that since these are interpretative regulations,* they were entitled to a trial *de novo*

* It has already been demonstrated, *supra*, that even within plaintiffs' own definitional distinctions whether this regulation is denominated "interpretative" or "substantive" will not alter its binding effect. This section will demonstrate that the "interpretative" or "substantive" distinction will not influence the standard of review.

before the district court (App. Brief, Point II). Secondly, and alternatively, plaintiffs argue that even if the standard of review to be applied is the substantial evidence (App. Brief, Point IV) or the arbitrary and capricious standard, that the whole record either was not before the District Court or that if the whole record was before the District Court, it was inadequate to support the Commissioner's action and should have been supplemented by the taking of the Commissioner's or his designee's deposition (App Brief, Points V and VI).

A. The appropriate standard of review of these regulations is the "arbitrary and capricious" standard provided for in the administrative procedure act.

The standard of review to be applied by the Court in reviewing these regulations is clearly set forth in the Administrative Procedure Act. Whether the regulation is considered interpretative or substantive the arbitrary and capricious standard provided for in 5 U.S.C. §§ 706(2)(A) through (D) is applicable. The substantial evidence test of 5 U.S.C. § 706(2)(E) applies only to regulations which by statute may not be enacted without a hearing.

> "Under the Administrative Procedure Act, a court reviews agency findings to determine whether they are supported by substantial evidence only in a case subject to the hearing provisions of 5 U.S.C. §§ 556 and 557 or 'otherwise reviewed on the record of an agency hearing provided by statute. . . .' 5 U.S.C. § 706(2)(E)."
>
> (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 n. 19 (1973) (holding that § 701(a) regulations are not subject to such review).

See also, Associated Industries of N.Y.S., Inc. v. *United States Department of Labor*, 487 F.2d 342, 347 (2d Cir.

1973). The *de novo* standard of review, Section 706(a)(F), is only applicable in two circumstances: first, where there has been an adjudicatory hearing and the fact-finding was inadequate and second, where relevant issues not before the agency are raised in a proceeding to enforce non-adjudicatory action. Those circumstances are not present here. *Compare, Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 415 (1971).

To support their contention that they are entitled to *de novo* review—a contention contrary to the express and explicit language of the Administrative Procedure Act—plaintiffs make reference to three cases. Each is not on point. *United States* v. *Everett Fisheries, Inc.*, 73 Cr. 109 (W.D. Wisc. May 30, 1973) involved a criminal prosecution arising from the violation of a regulation concerning sanitary conditions which used such terms as "readily cleanable," "adequately washed" and "adequately inspected." Those terms were not precise and were subject to interpretation and argument. When a regulation is precise, as here, the only issue in an enforcement proceeding would be whether it had been violated. *United States* v. *Bodine Produce Co.*, 206 F. Supp. 201, 208 (D. Ariz. 1962). The distinction made here between precise and imprecise regulations has been recognized in a case involving Section 701(a) regulation by the Supreme Court as affecting the judicial standard of review. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 621 n. 17 (1973).

Plaintiffs' second citation is to *Salazar* v. *Hardin*, 314 F. Supp. 1247 (D. Col. 1970). In that case, plaintiffs challenged as contrary to statute a regulation of the Secretary of Agriculture. Mention is made in the course of the opinion of a trial, although the nature or purpose of the trial is not clarified. Nonetheless, the case does not stand for the proposition that a trial *de novo* is appropriate. The key words in the phrase "trial *de novo*" are the latter two.

which indicate that the Court's review is based upon its evaluation of the facts, not the agency's. In *Salazar*, the Court did not take a *de novo* approach, but instead indicated that "weight must be given to the administrator's interpretation of applicable statutes" except where the regulation is "plainly inconsistent" with the statute. 314 F. Supp. at 1258.

In the footnote on page 29 of their brief plaintiffs refer to a comment by Judge Friendly in *National Nutritional Food Association* v. *Food and Drug Administration*, 491 F.2d 1141 (2d Cir. 1974) indicating that in the *Toilet Goods Ass'n* v. *Gardner case*, 360 F.2d 677 (2d Cir. 1966) *aff'd* 387 U.S. 167 (1967), if the Government's motion to dismiss were not granted, both sides contemplated a trial. That comment was in reference only to Count Four of the complaint which was held to involve a regulation so indefinite as to make application of the declaratory judgment procedures inappropriate. Given this indefiniteness, the Court held that review could only be based upon a factual record developed *after* application of the regulation on a case-by-case basis. Here, of course, there is no such problem.

In sum, there is no authority for the proposition that review in this case is to be based on a substantial evidence test or is to be *de novo*. Rather the standard is whether the Commissioner's action can be deemed arbitrary and capricious.

In determining whether the Commissioner's action was arbitrary and capricious, "the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 415 (1971). Moreover, as the Supreme Court noted:

> "[T]he ultimate standard of review is a narrow one. This court is not empowered to substitute its judgment for that of the agency" (401 U.S. at 416).

Indeed as this Circuit has recently held, the record required under the arbitrary and capricious standard need not be as complete as would be required under the substantial evidence standard. "[I]t is sufficient that the regulations be supported by evidence in the Commission's files, or even by its experience." *Consumers Union of United States, Inc.* v. *Consumer Products Safety Commission,* 491 F.2d 810, 812 (2d Cir. 1974).

B. The district court's vacation of the deposition notice served by plaintiffs upon defendant Schmidt was proper.

Review under the Administrative Procedure Act is limited to the record. The cases make clear that the record referred to is the existing one. The validity of the regulation stands or falls on that record. In *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402, 419 (1971), the Supreme Court discussed a record review "based on the full administrative record that was before the Secretary at the time he made his decision." More recently, the Supreme Court in *Camp* v. *Pitts,* 411 U.S. 138, 142 (1973) noted that under Administrative Procedure Act review, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." The record filed with the Court has been accurately described by Judge Frankel as "voluminous and unstinting" (383a).

Although discovery may be appropriate when there is no record from which the Court may determine the basis for the administrative decision, when there is a record, as there abundantly is here, and because "inquiry into the mental processes of administrative decision makers is usually to be avoided", "there must be a strong showing of bad faith or improper behavior before such inquiry may be made." *Citizens to Preserve Overton Park* v. *Volpe, supra,* at 420. In this case there has not even been an

allegation of bad faith or improper motive. All that is sought is an inquiry into the mental processes of the defendants. That is not permissible. *National Nutritional Foods Association, Inc.* v. *Food and Drug Administration*, 491 F.2d 1141 (2d Cir. 1974).

POINT III

The administrative record supports the regulations.

A. At the regulated levels vitamins A and D are properly classified as drugs.

It is agreed by both sides that requisite to a limitation of sale by prescription pursuant to 21 U.S.C. § 353(b) is a determination that the item so regulated is a "drug" within the meaning of the Federal Food, Drug and Cosmetic Act. Plaintiffs contend that the classification by the Commissioner of Vitamins A and D, which plaintiffs deem common food items, as drugs is "beyond the scope of any legal authority", "without statutory authority" and arbitrary. They claim that these vitamins are food and not drugs.*

On this appeal, plaintiffs assert that this precise question (i.e. whether vitamins are "drugs") was presented to this Court *National Nutritional Foods Association* v. *Food and Drug Administration*, 73-2129, et al. (2d Cir. August 15, 1974). While we do not agree with this contention, even if "identical theories" are presented in both cases, the dicta in this Court's opinion of August 15, 1974 is supportive, if not completely dispositive, of the position of

* Plaintiffs themselves contradict this argument when they suggest that these massive dosages of Vitamins A and D should be regulated under § 502(f) of the Act, 21 U.S.C. § 352(f), relating to the labeling of *drugs*.

the defendants here. In its August 15, 1974 opinion this Court rejected a provision of an FDA regulation not involved in this case to the effect that most preparations containing in excess of 150% of the RDA of any vitamin are drugs. In essence the Court ruled that the hearing record in that proceeding was insufficient to establish that all vitamin and mineral products with potencies in excess of 150% of the U.S.R.D.A. were necessarily therapeutic products. Nevertheless, the opinion carefully noted:

> "Our invalidation of this subsection in no way prevents high-dosage products properly labeled from being marketed as over-the-counter drugs." (Slip opinion, 5253)

Thus, explicitly this Court has recognized that vitamins may be considered drugs. However, in the event that we have misread the Court's decision of August 15, 1974, there are persuasive reasons for upholding the defendants' position that, for purposes of this appeal, vitamins may be treated as a species of drug.

Judge Frankel found: "The products here are squarely within the literal language and meaning of the statute" (340a-341a), which defines drugs as follows:

> "The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formula, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories." (21 U.S.C. § 321(g)(1))

Vitamins A and D fit both within subsection (A) and subsection (B) of the just-quoted definition.

Vitamins A and D are recognized in the official United States Pharmacopoeia and in the official National Formulary, and thus both are subject to regulation as drugs as a matter of law. See 21 U.S.C. 321(g)(1)(A) (296a, 307a-310a, 311a-319a); *United States* v. *Dianovin*, 475 F.2d 100 (1st Cir. 1973) (Vitamin K regulated as a drug); *United States* v. *Articles of Drugs*, 263 F. Supp. 212, 215 (D. Neb. 1967) (item appearing in United States Pharmacopoeia is a drug as a matter of law).

Subsection (B) of Section 321(g)(1) defines drugs by virtue of their intended use, i.e. "in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." The Commissioner noted in the initial publication of these regulations the FDA's concern and the concern of medical authorities over "the widespread promotion to the laity of excessive quantities of these vitamins for prophylaxis and treatment of a variety of diseases and disorders" appearing in the lay press and on radio and television (35a).

Furthermore, the Commissioner of Food and Drugs has concluded on the basis of the record that the high dosage preparations of vitamins A and D involved in these regulations, which exceed by far any routine dietary use for these vitamins, are appropriate only for treating medical conditions and not as dietary supplements.

> "No evidence was submitted in the comments to establish a food or nutritional use of vitamin A or vitamin D at higher levels, except for a limited number of persons with poor vitamin D absorption who need up to 1,000 I.U. of this vitamin for nutritional purposes under medical supervision. With that one exception, which is recognized in the revised regulation, intake of vitamins at levels exceeding the

upper limits as specified in § 80.1 are therefore appropriate only for therapeutic purposes and thus are properly classed as drugs" (32a).

Thus, such high dosages of vitamins A and D are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B) in that they are only appropriate for use in the "cure, mitigation, treatment, or prevention of disease."*

It is well established that the term "drug" as defined in the Federal Food, Drug, and Cosmetic Act is a broad term of art, not to be limited to a restrictive meaning, but rather to be "given a liberal construction consistent with the Act's overriding purpose to protect the public health." *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 792, 798 (1969).

As numerous decisions attest, there is nothing inconsistent about a "common food item" also classified as a drug under the Act. E.g. *United States* v. *Vitasafe Corp.*, 345 F.2d 864 (3d Cir.), *cert. denied*, 382 U.S. 918 (1965). The key to classification is the purpose for which the item is to be utilized. *See, e.g., United States* v. *Hohensee*, 243 F.2d 367 (3d Cir. 1957), *cert. denied*, 353 U.S. 976 (1957). ("peppermint tea; wheat germ oil"); *Kordel* v. *United States*, 335 U.S. 345 (1948) ("health foods", "compounds of various vitamins, minerals and herbs").

"[T]he interpretation of even definitional sections in the drug law will often involve expert knowledge and the ability to evaluate the scientific evidence that becomes relevant." *Bradley* v. *Weinberger*, 483 F.2d 410 (1st Cir. 1973). The United States Supreme Court has very recently emphasized the propriety of the issuance of regula-

* Subsection (B) of 21 U.S.C. § 321(g)(1) makes no exception for food as Subsection (C) does.

tions by the Food and Drug Administration; the exercise of pharmocological, chemical and medical expertise in the promulgation and interpretation of those regulations, and the need for judicial deference to the expertise of the FDA. *Supra,* pp. 15 to 16.

Thus, the Commissioner's classification of Vitamins A and D at the specified dosage levels as "drugs" comports with the purpose of the Act, and should not be "second-guessed" (*United States* v. *An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 792 (1969) if "not unreasonable." (*Udall* v. *Tallman,* 380 U.S. 1, 16-18 (1965).

B. The commissioner neither exceeded his statutory authority nor acted in an arbitrary and capricious manner in classifying vitamins A and D as prescription drugs pursuant to 21 U.S.C. §353.

Plaintiffs claim that the Commissioner exceeded his authority and/or acted arbitrarily and capriciously in classifying Vitamins A and D as prescription drugs at these particular levels. The claim is meritless.

The statute, 21 U.S.C. §353(b)(1)(B) defines a prescription drug as one which "*because* of its toxicity or other potential harmful effect, or the method of its use . . . is not safe for use except under the supervision" (emphasis added) of a physician. Both at the time of the notice of proposed rulemaking and to a greater extent at the time the rule became effective, the Commissioner had before him a substantially uncontradicted body of medical opinion, supported by studies, that use of Vitamins A and D in large quantities is dangerous and may result in serious injury to health or death (35a, 33a; Exhibits Volumes I and II); that people who had purchased these vitamins on a non-prescription basis had in fact consumed them in unusually large quantities and had become sick; and that,

in light of recent publicity encouraging people to ingest large quantities of vitamins for health reasons, danger of similar episodes in the future was only likely to increase.

Of course, implicit in the promulgation of the regulation is a finding that at the prescription level set these vitamins have a potentially for harm and are not safe for use except under supervision of a practioner.

We do not understand plaintiffs to contest the toxicity of these vitamins at high levels (29a-31a) and accordingly it would appear that all parties agree that Vitamin A and Vitamin D, at least in large dosages, fall squarely within the above quoted definition of a prescription drug (assuming that Vitamin A and D are drugs).

Plaintiffs' argument appears to be that, while Vitamin A is unsafe in such quantities as 50,000 to 100,000 IUs and Vitamin D is unsafe in large quantities, the defendants acted arbitrarily in requiring a prescription when purchasing pills containing only 10,000 and 400 IU's of the respective drugs (App. Brief, Point I).

First of all, it is appropriate to point out that the FDA is the agency to which Congress delegated the responsibility of protecting the public from indiscriminate sale and use of potentially harmful drugs, and it is the FDA which had developed the expertise necessary to properly discharge this responsibility. The judgments of the FDA are, of course, not immune from judicial scrutiny. However, the line-drawing—i.e. the exact number of IUs of Vitamin A and Vitamin D which make those drugs unsafe except under supervision of a physician—which plaintiffs now attack, is precisely the kind of question which is within the discretion of the FDA and which should be overturned only if irrational. *Mississippi Valley Barge Line Co.* v. *United States*, 292 U.S. 282, 286 (1934); *Universal Camera Corp.* v. *N.L.R.B.*, 340 U.S. 474 (1951). Nor does the ad-

monition against substitution of judicial judgment for agency judgment become inoperative because two inconsistent conclusions could have been drawn from the evidence before the agency. *Illinois Central R.R. Co.* v. *Norfolk & Western Ry. Co.*, 385 U.S. 57 (1966) (applying a substantial evidence test).

When, as here, the record contains conflicting evidence, it is the duty of the FDA to evaluate such conflicting evidence. *Weinberger* v. *Bentex Pharmaceuticals*, 412 U.S. 645, 653 (1973). The Commissioner did precisely that and made the required judgment:

> "The Commissioner has carefully reviewed the comments and analysis regarding the medical/scientific justification for establishing the proposed vitamin A and vitamin D limits and finds that such comments do not sufficiently support a revision of the proposed limits. No evidence refuted the toxicity findings on which the proposal was based and further reports of toxicity continue to accumulate. Based on consultation with the most knowledgeable experts available, the Commissioner finds that the scientific consensus is that the proposed limits are appropriate at this time."

We submit that the agency determination was entirely rational even assuming, as the plaintiff's assert, that it is dangerous neither to take 10,000 IUs of Vitamin A nor 400 IUs of Vitamin D. The Commissioner was legitimately concerned that buyers of Vitamins A or D would not limit themselves to one pill per day (E. 256, E. 258, E. 275-276, E. 363). If the Commission were required to adopt plaintiff's view, that prescriptions are only permissible if each pill contains a dangerous quantity of a vitamin, that would withdraw from the public the protection which the FDA seeks to give by its regulation and wholly overlooks the fact that people often take more than one pill per day.

The observation that foods contain large quantities of Vitamin A simply serves to demonstrate that many people consume large quantities of Vitamin A in their daily diets,* thereby increasing the danger of illness from whatever additional amounts they take in pill form. The Commissioner could properly consider the ease of ingestion of vitamins in the form of pills and consumer dietary habits in determining that these articles ought to receive a treatment different from foods containing Vitamins A and D:

> "The convenience of ingestion in this form on a routine basis encourages excessive intake of these vitamins far beyond the average amounts ingested in normal diets of conventional food over extended periods of time. Adequate amounts of Vitamin A and Vitamin D will continue to be available as dietary supplements and are not being removed from the market place" (33a).

These other factors bear on which mode of regulation the Commissioner chose to utilize.** But in any event, the regulation is not infirm because the Commissioner conceivably could have proceeded in another fashion:

---

* Nor would it be correct to conclude that the presence of Vitamin A in foods is necessarily evidence of the safety of its ingestion in pill form. Vitamin A can be present in foods preformed, but it often appears as a provitamin A carotenoid, which only becomes active after absorption through the intestinal wall (55a). The most common carotenoid, carotene, ingested "in massive doses is not converted to Vitamin A rapidly enough to induce toxicity, but the excess carotene accumulates in the body without producing clinical systems other than yellow skin. This quickly returns to normal when carotene ingestion is stopped" (57a).

** Plaintiffs repeatedly suggest that the FDA should have solved the admitted problem of toxicity of Vitamins A and D at high dosages by labeling the vitamins and selling them as over-the-counter drugs. Of course, the proffer of the alternative form of regulation is a concession that vitamins are drugs. However, focusing on the suggestion itself, the first response, apart from

[Footnote continued on following page]

"Given that some remedial measure was authorized, the question remaining is whether the measure chosen is reasonably related to its objectives . . . That some other remedial provision might be preferable is irrelevant. We have consistently held that where reasonable minds may differ as to which of several remedial measures should be chosen, courts should defer to the informed experience and judgment of the agency to whom Congress delegated appropriate authority. *Northwestern Co.* v. *Federal Power Commission,* 321 U.S. 119, 124 (1944); *National Broadcasting Co.* v. *United States,* 319 U.S. 190, 224 (1943); *American Telephone and Telegraph Co.* v. *United States,* 299 U.S. 232, 236 (1936)." *Mourning* v. *Family Publications Service, Inc.,* 411 U.S. 356 (1973).

---

the legal principle that it is for the agency to choose between the alternatives provided to it by Congress, is that labeling with adequate directions for use is only an appropriate solution when there is a safe use for the item. In this case, what the Commissioner in effect determined was that the only adequate direction was "Do not use except under the care of a physician." Moreover, as recently as August of this year, this Court stated in a different, but related context, that "it was far from irrational, at least as a general matter, for the agency to conclude that no label statement could fully meet this problem. Striking a proper balance among the interests of sophisticated and unsophisticated consumers is for the agency, not for the reviewing court." (*National Nutritional Foods Association* v. *Food and Drug Administration,* 73-2129 et al., p. 5238 (2d Cir. August 15, 1974). Here the evidence before the Commissioner was clear that persons were not in fact abiding by the instructions on the label. For example, plaintiff Solgar's label on 50,000 IU capsules of Vitamin A directs: "One capsule daily or as directed by physician (325a). The Commissioner recognized that such directions have a less inhibiting effect than labels containing warnings on toxicity and a legend, "caution: Federal law prohibits dispensing without a prescription." But this concession hardly vitiates the propriety of the Commissioner's decision to regulate massive doses of Vitamins A and D as prescription drugs. Plaintiffs' suggestion to the contrary is without legal or evidentiary support (App. Br. 17).

There can be no question but that the regulation is reasonably related to the statutory purpose "to protect the public from abuses in the sale of potent prescription medicines." Senate Report No. 946, 82d Cong., 1st Sess. (1951) (283a).

The Commissioner is not required to set the prescription level at maximum tolerance or, to cite the language of the Court in *United States* v. *1,950 Boxes of Macaroni*, 181 F.2d 427 (N.D. Ill. 1910), is he required to engage in "hair-splitting speculation as to whether the amount of poison used may possibly have been so nicely calculated as not to kill or be of immediate serious injury" and the exercise of "great caution but serves to emphasize the reasonableness of the Administrator's conduct." *Atlas Powder Co.* v. *Ewing*, 201 F.2d 347, 355 (3rd Cir. 1952), *cert. denied*, 345 U.S. 923 (1953):

> "The margins of safety provided in the levels established by this proposal were developed to take into account the wide ranges of vitamin content in foods and the dosage levels of vitamin A and vitamin D preparations that are usually implicated in toxic conditions" (33a).

Plaintiffs argue further that the Regulations are invalid because the Commissioner did not make a finding as to the specific level at which Vitamins A and D were toxic. The legislative history eliminates any doubt that a finding of toxicity is not a *sine qua non* for regulation by prescription:

> "The word 'safe', as used in the definition, is intended to have its ordinary meaning. For example, nontoxic drugs like quindine sulfate, intended for heart disease, or penicillin, for infections, are not safe for self-medication because their unsupervised use may indirectly cause injury or death. *The language of the definition clearly shows that toxicity is only one factor to be considered* by the courts in determining whether a particular drug is safe for

> use without medical supervision. The definition requires the court to consider also other potentialities for harmful effect, the method by which the drug is used, and the collateral measures that may be necessary in order to use the drug safely. When this language is given judicial interpretation consistent with the over-all purpose of the Federal Food, Drug, and Cosmetic Act to protect the public health it will effectively restrict to prescription sale all drugs that require professional supervision for their use." (Senate Report) (emphasis added) (286a).*

To reiterate, the prescription provision regulates that drug which "because of its toxicity or other potentiality for harmful effect" should only be consumed under the care of a physician.

Plaintiffs' citation to *United States* v. *An Article of Drug . . . Decholin,* 264 F. Supp. 473 (E.D. Mich., 1967) is inapposite. In *Decholin* there was no evidence of toxicity of the drug at any dosage level or that anyone had ever been harmed by the active ingredient; the only toxicity or potentiality of toxicity of the substance in question was "theoretical." (264 F. Supp. 478). Here, unlike *Decholin,* the record undisputably contains evidence supporting the potential for harmful consequences required by the Court in *Decholin* (264 F. Supp. at 480).

---

* *Contra, American Pharmaceutical Association* v. *Weinberger,* 148-73 (D.D.C. June 5, 1974), cited by plaintiffs (App. Br. 18) in which the Court struck down the effort of the FDA to control the distribution channels of methadone to guard against diversion under its power to condition the granting of a new drug application upon submission of tests showing whether the new drug is "safe for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof." That decision did not reject the regulation of methadone as a prescription drug.

In sum, where, as here, the Agency, in making complex medical and scientific judgments within the scope of its expertise, has reviewed the pertinent scientific literature and sought and reviewed the comments of the public, both lay and professional, and its ultimate judgment is within the scope of alternatives supported by the comments, and indeed is specifically supported by such expert professional organizations as the American Academy of Pediatrics and the American Medical Association, the Agency cannot be said to have acted in an arbitrary or capricious manner.

CONCLUSION

For the reasons set forth above, the order of the District Court should be affirmed.

Respectfully submitted,

PAUL J. CURRAN,
United States Attorney for the Southern District of New York,
Attorney for Defendants-Appellees

NAOMI REICE BUCHWALD,
GERALD A. ROSENBERG,
Assistant United States Attorneys,
Of Counsel.

★ U. S. Government Printing Office 1974— 614—052—74

Form 280 A-Affidavit of Service by Mail
Rev. ^/72

CA 74-1738

AFFIDAVIT OF MAILING

State of New York)
County of New York) ss

Pauline Troia, being duly sworn, deposes and says that she is employed in the Office of the United States Attorney for the Southern District of New York.

That on the 11th day of October 1974 s he served two copies of the within

Government's brief

by placing the same in a properly postpaid franked envelope addressed:

1) Bass & Ullman, Esqs.,
747 Third Ave.
New York, NY 10017

2) Kirkpatrick W. Dilling, Esqs.,
188 West Randolph St.
Chicago Ill. 60601

And deponent further says s he sealed the said envelope s and placed the same in the mail chute drop for mailing in the United States Courthouse, Foley Square, Borough of Manhattan, City of New York.

Pauline Troia

Sworn to before me this

11th day of Oc tober 19 74

Walter G. Brannon

WALTER G. BRANNON
Notary Public, State of New York
No. 24-0394500
Qualified in Kings County
Cert. filed in New York County
Term Expires March 30, 1975